



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,876	03/15/2004	Sharen A. Godwin	5714-001	1938
25184	7590	10/06/2009		
WILLIAM J. MASON MACCORD MASON PLLC POST OFFICE BOX 1489 WRIGHTSVILLE BEACH, NC 28480				
EXAMINER				
PASS, NATALIE				
ART UNIT		PAPER NUMBER		
3686				
MAIL DATE		DELIVERY MODE		
10/06/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,876

Applicant(s)

GODWIN ET AL.

Examiner

Natalie A. Pass

Art Unit

3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 27 May 2009. Claims 2-4 have been cancelled. Claims 1, 8, 14-16 have been amended. Claims 1, 5-20 are pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 5-20 are rejected under 35 U.S.C. § 101 for substantially the same reasons given in the previous Office Action (paper 20090302). Further reasons appear hereinbelow.

A) The method steps of claims 1, 5-20, continue to fail the first prong of the new Federal Circuit decision, as discussed in paper 20090302, since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. In particular, Applicant's claims continue to not recite who or what is performing the method steps. Moreover, as regards the second prong of the new Federal Circuit decision, the method steps still fail to unambiguously require transformation of underlying subject matter to a different state or thing. In other words, there is no machine or transformation present in the claims. Thus, claims 1, 5-20 are non-statutory since they are not requisitely tied to another statutory class and they do not requisitely transform underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 112

4. The rejections of claims 1-7, 14-15 under 35 U.S.C. 112, second paragraph, as being indefinite are hereby withdrawn due to the amendment filed 27 May 2009.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al., U.S. Patent Application Publication Number 2003/0046114, for substantially the same reasons given in the previous Office Action (paper 20090302), and further in view of McAlindon, et al., U.S. Patent Number 7251609. Further reasons appear hereinbelow.

(A) Claim 1 has been amended to include the recitation of

- "inputting a search criteria based on participant criteria into the data source to select the records of patients that potentially meet said criteria, the patients being identified by non-personal identifiers," in lines 7-9; and

- "non-personal," in line 10; and
- "receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial" in lines 12-13.

As per these new limitations, Davies teaches a method as analyzed and discussed in the previous Office Action (paper number 20090302) further comprising

inputting a search criteria based on participant criteria into the data source to select the records of patients that potentially meet said criteria, the patients being identified by non-personal identifiers (Davies; Abstract, paragraphs [0013]-[0015], [0018], [0025]-[0026], [0063], [0086]); and

transmitting said non-personal patient identifiers to said healthcare professional to enable said healthcare professional to contact said patients regarding said clinical trial (Davies; paragraphs [0032], [0053]- [0055], [0086]).

Davies fails to explicitly disclose receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial.

However, the above features are well-known in the art, as evidenced by McAlindon.

In particular, McAlindon teaches receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial (McAlindon; column 4, lines 26-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Davies to include these limitations, as taught by McAlindon,

with the motivations of “recruiting and screening for candidates who are eligible to participate in a clinical trial” (McAlindon; Abstract).

The remainder of claim 1 is rejected for the same reasons given in the prior Office Action (paper number 20090302, section 6, pages 4-5), and incorporated herein.

(B) The amendments to claim 8 repeat the features of amended claim 1, and are therefore rejected for the same reasons given above in the rejections of claims 1, and incorporated herein.

(C) As per the amendments to claims 14-15, these appear to have been made merely to correct minor typographical or grammatical errors or to overcome claim objections or rejections under 35 USC § 112. While these changes render the language of the claim smoother and more consistent, they otherwise affect neither the scope and breadth of the claim as originally presented nor the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action.

As such, the recited claimed features are rejected for the same reasons given in the prior Office Action (paper number 20090302), and incorporated herein.

The remainder of claims 14-15 is rejected for the same reasons given in the prior Office Action (paper number 20090302, section 7, page 7), and incorporated herein.

(D) As per the amendments to claim 16, these appear to have been made merely to correct minor typographical or grammatical errors. While these changes render the language of the claim smoother and more consistent, they otherwise affect neither the scope and breadth of

the claim as originally presented nor the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action.

As such, the recited claimed features are rejected for the same reasons given in the prior Office Action (paper number 20090302), and incorporated herein.

The remainder of claim 16 is rejected for the same reasons given in the prior Office Action (paper number 20090302, section 9, pages 8-10, and incorporated herein.

The motivations for combining the respective teachings of Davies and McAlindon are as given in the rejection of claim 16 in the prior Office Action (paper number 20090302) and incorporated herein.

(E) Claims 5-7, 9, 10, 11-13, 17-20 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 20090302, section 6, pages 5-6, and section 9, pages 10-11), and incorporated herein.

Response to Arguments

7. Applicant's arguments filed 27 May 2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 27 May 2009.

(A) At pages 6-8 of the 27 May 2009 response, Applicant argues the rejection of method claims 1, 5-20 under 35 U.S.C. § 101. These arguments are not persuasive. In particular,

Applicant's claims continue to not recite who or what is performing the method steps, and moreover, Examiner submits that there is neither machine nor transformation, as analyzed in the new Federal Circuit decision, present in the claims.

8. The remainder of Applicant's arguments filed 27 May 2009 have been fully considered but they are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. **Any response to this final action should be mailed to:**

Box AF
Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to: (571) 273-8300.

For formal communications, please mark "EXPEDITED PROCEDURE".

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/N. A. P./
Examiner, Art Unit 3686
September 30, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686